

CLAIM 1

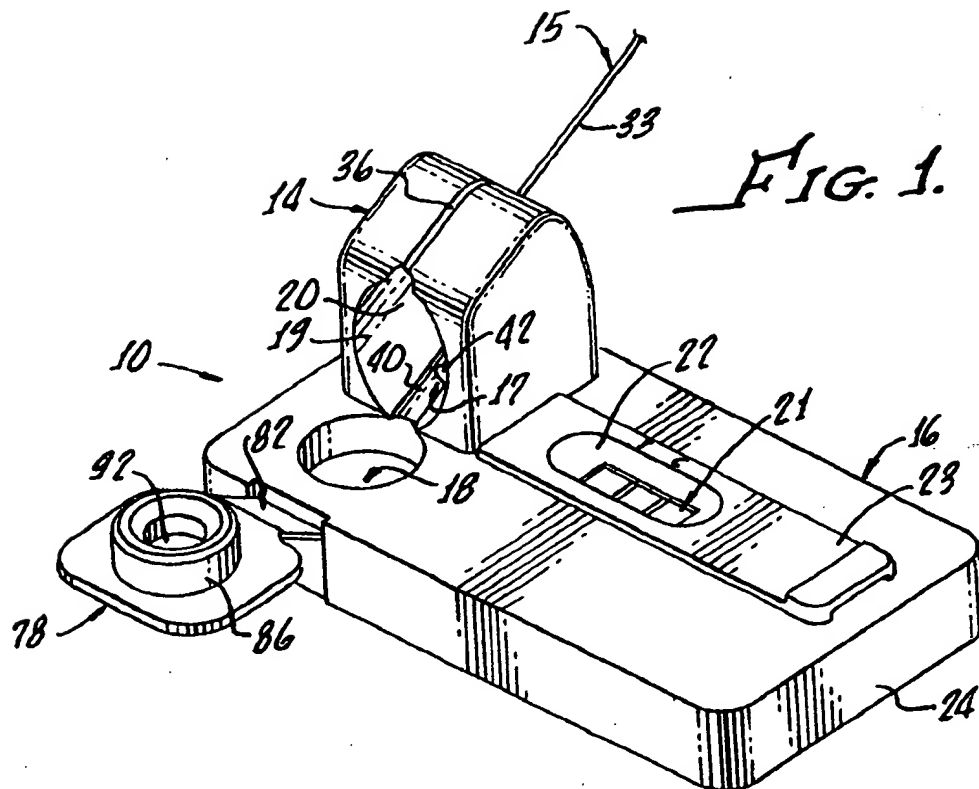
Applicants claim, in claim 1, a specimen collecting and testing device comprising an elongate, hollow housing having a proximal end and a distal end and a hollow portion; at least one test membrane or sample collecting strip positioned within the hollow portion of the housing; a fluid chamber, for holding specimen, positioned adjacent to the test membrane or sample collecting strip; at least one elongate handle member, having a proximal end and a distal end, slidably received in the hollow portion of the housing; and a foam member, for collecting specimen, extending from the proximal end of the handle. According to claim 1, when the handle is drawn through the housing, collected specimen is deposited from the foam member into the fluid chamber and onto the test membrane or sample collecting strip.

The Bachand reference, on the other hand, describes a saliva testing and confirmation device that includes an expressor cup 14 mounted on a testing and confirmation platform 16. A test strip 21 is mounted in the platform 16. According to the Bachand, a collection swab 15 is used to collect a specimen. The swab is then inserted into the expressor cup 14 where it is compressed, causing specimen to flow onto test strip 21.

In paper 4, the Office asserted that:

Bachand et al teach a specimen collecting and testing device having an elongated hollow housing with a test membrane (21), a fluid chamber (26), an elongated handle (33) with an absorbent member (32) for collecting the sample. The handle (33) is pulled through slot (36) into expressor port (20) where the sample is squeezed from the member (32) [see page 3 column 1].

As Applicants understand it, the Office asserts that Bauchand describes and shows an "elongate, hollow housing" in elements 14 (expressor) and 16 (platform). Thus, according to the Office, Bauchand's "elongate, hollow housing" is the expressor 14 and platform 16 shown below:



This "elongate, hollow housing" is clearly different than that taught by Applicants. In particular, Applicants require in claim 1 that:

- (a) the test membrane or sample collecting strip is positioned within the hollow portion of the housing; and
- (b) the elongate handle member is slidably received in the hollow portion of the housing.

Thus, Applicants require that both the test membrane/sample collecting strip and the handle member is positioned in the hollow portion of the housing.

The Bauchand reference does not describe or otherwise suggest such a device. Rather, the device described by Bauchand has a test membrane 21 positioned in the platform 16 (one portion of the housing) and a handle member (fluid collection element 15) received in an opening in the expressor 14 (another separate portion of the housing).

As provided in MPEP-2131, a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegal Bros. V. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Or stated another way, "The identical invention must be shown in as complete detail as is contained in the ... claims. *Richardson v Suzuki Motor Co.*, 868 F.2d 1226, 9 USPQ 2d. 1913, 1920 (Fed. Cir. 1989). Although identity of terminology is not required, the elements must be arranged as required by the claim. *In re Bond*, 15 USPQ2d 1566 (Fed. Cir. 1990).

Clearly, the Bauchand reference does not describe each and every element as set forth in claim 1 nor are the elements of the Bauchand reference arranged as required by claim 1. In particular, Bauchand fails to describe a test membrane or sample collecting strip is positioned within the hollow portion of the housing and an elongate handle member slidably received in the hollow portion of the housing. Accordingly, the §102(e) rejection cannot be maintained.

Further, it is well-established that to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). MPEP 2142.

As set out above, the Bauchand reference does not teach or suggest all the claim limitations. Rather, according to the Office, Bauchand describes a platform 16 and expresser 14 which, together, form the "elongate, hollow housing". The test strip 21 is positioned in the surface of the platform 16 portion of the "housing", while the

handle (fluid collection element) 15 is received in the expresser 14 portion of the housing. This combination of the expresser 14 mounted on the platform 16 with the test strip 21 in the platform 16 and the handle (fluid collection element) 15 received in the expresser 14 is important, as specifically set out by Bauchand:

The device generally comprises an expresser, including a generally cup-shaped member having a distal opening adapted to receive a fluid collection swab.\* \* \* the expresser provides means for expressing at least a portion of the fluid specimen from the swab.\* \* \*

Importantly, the device further comprises a testing and confirmation platform fixed to the expresser. The platform provides both testing means for testing a portion of the fluid specimen and confirmation means for storing apportion of the fluid specimen for later testing or confirmation. (page 1, col. 2, lines 13-32)

Further:

The platform 16 is adapted to receive at least one test element 21.  
(page 2, col. 2, lines 50-60)

There is absolutely no suggestion or motivation in the Bauchand reference to modify the Bauchand arrangement as required by Applicants' claim 1. Rather, this suggestion and motivation comes purely from the Applicants' disclosure.

It is well-established that "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). Applicants respectfully submit that the only way that the 35 U.S.C. §102 and §103 rejections could be maintained would be to impermissibly ignore limitations of claim 1.

#### CLAIM 27

Applicants claim, in claim 27, a specimen collecting and testing device comprising (a) a sample collecting mechanism and (b) a sample testing mechanism. As set forth in claim 27, the sample collecting mechanism comprises an elongate, hollow housing having a proximal end and a distal end and a hollow portion; an elongate handle member slidably mounted within the hollow portion of the housing; and a foam member for collecting specimen extending from the proximal end of the handle. The sample testing mechanism comprises at least one test membrane or

sample collecting strip carrying diagnostic test chemistry positioned within the hollow portion of the housing.

Thus, according to claim 27, the sample collecting, which is the portion of the device used to collect a specimen, includes the housing, the handle and the foam member. The testing mechanism includes the test strip.

The Bauchand reference, on the other hand, according to the Office describes a "housing" that comprises the expresser 14 and the platform 16, a swab (handle with foam member) 15 and a test strip 21. According to Bauchand, the sample collecting mechanism is only the swab 15 and does not, nor could it, include the "housing". Rather, the swab 15 is picked up alone and is touched to the sampled material. According to Applicants' invention, on the other hand, the housing having the handle with foam member held inside of it, is picked up with the handle and foam member extending out of the proximal end of the housing (See Fig. 2) and the foam member is touched to the material being sampled. Thus, the Bauchand reference does not describe or suggest a device comprising a sample collecting mechanism that includes a housing having a hollow portion, an elongate handle member slidably mounted within the hollow portion of the housing and a foam member for collecting specimen extending from the proximal end of the handle.

Further, there is absolutely no motivation or suggestion in the Bauchand reference to modify the Bauchand arrangement as required by Applicants' claim 27. Rather, Bauchand specifically teaches and describes a platform 16 having an expresser 14 mounted on it and a swab 15. There is no suggestion or motivation to move the test strip 21 out of the platform 16, eliminate the platform 16 completely and place the test strip 21 within the expresser 14. Rather, this suggestion and motivation comes purely from the Applicants' disclosure.

It is well-established that "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). Applicants respectfully submit that the only

way that 35 U.S.C. §102 and §103 rejections could be made against claim 27 would be to impermissibly ignore limitations of claim 27.

### CLAIM 30

Applicants claim, in claim 30, a specimen collecting and testing device comprising an elongate, hollow housing having a proximal end and a distal end; an elongate handle member having a proximal end and a distal end, the handle member slidably mounted within the housing; the elongate handle member and housing being coaxial; a foam member for collecting specimen extending from the proximal end of the handle; and at least one test membrane or sample collecting strip carrying diagnostic test chemistry positioned within the housing.

The Bauchand reference does not describe or suggest such a device. In particular, Bauchand fails to describe or suggest an elongate, hollow housing having an elongate handle member slidably mounted within the housing, wherein the elongate handle member and housing are coaxial and, further, wherein the test membrane or sample collecting strip is positioned within the housing. Rather, the Bauchand reference describes a platform 16 having an expresser 14 mounted thereon which, the Office asserts, is a "housing". As shown and described by Bauchand, the handle of the swab 15 is received in the expresser 14 portion of the "housing" and is not, in any way, coaxial with the housing.

Thus, claim 30 is clearly patentable over the Bauchand reference.

### CONCLUSION

Reconsideration and allowance of claims 1-25 is respectfully requested in view of the foregoing discussion. This case is believed to be in condition for immediate allowance. Applicant respectfully requests early consideration and allowance of the subject application.

If for any reason a fee is required, a fee paid is inadequate or credit is owed for any excess fee paid, you are hereby authorized and requested to charge Deposit Account No. **04-1105**.

Should the Examiner wish to discuss any of the amendments and/or remarks made herein, the undersigned attorney would appreciate the opportunity to do so.

Date: May 13, 2003

Respectfully submitted,



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**VERSION WITH MARKINGS TO SHOW CHANGES MADE IN CLAIMS**

Please note that additions to the claims are shown underlined and deletions are shown in brackets.

1. A specimen collecting and testing device comprising:  
an elongate, hollow housing having a proximal end and a distal end and a hollow portion;  
at least one test membrane or sample collecting strip positioned within the hollow portion of the housing, the test membrane carrying diagnostic test chemistry;  
a fluid chamber, for holding specimen, positioned adjacent to the test membrane or sample collecting strip;  
at least one elongate handle member, having a proximal end and a distal end, slidably received in the hollow portion of the housing; and  
a foam member, for collecting specimen, extending from the proximal end of the handle whereby, when the handle is drawn through the housing, collected specimen is deposited from the foam member into the fluid chamber and onto the test membrane or sample collecting strip.

Please add the following new claims:

26. The specimen collecting and testing device of claim 1, wherein the elongate handle member is slidably received in the same hollow portion of the housing as the test membrane or sample collecting strip is positioned.
27. A specimen collecting and testing device comprising:
  - a. a sample collecting mechanism comprising:  
an elongate, hollow housing having a proximal end and a distal end and a hollow portion;  
an elongate handle member slidably mounted within the hollow portion of the housing;  
a foam member for collecting specimen extending from the proximal end of the handle; and



b. a sample testing mechanism comprising:  
at least one test membrane or sample collecting strip carrying diagnostic test chemistry positioned within the hollow portion of the housing.

28. The specimen collecting and testing device of claim 27 further comprising a sample extraction mechanism comprising: the elongate hollow housing, whereby when the handle is drawn through the housing, collected specimen is extracted from the foam member and deposited onto the test membrane or sample collecting strip.

29. The specimen collecting and testing device of claim 27, wherein the elongate handle member and housing are coaxial.

30. A specimen collecting and testing device comprising:  
an elongate, hollow housing having a proximal end and a distal end;  
an elongate handle member having a proximal end and a distal end, the handle member slidably mounted within the housing;  
the elongate handle member and housing being coaxial;  
a foam member for collecting specimen extending from the proximal end of the handle; and  
at least one test membrane or sample collecting strip carrying diagnostic test chemistry positioned within the housing.